

## The Ultimate Company Announcement Service

M.L. Laboratories PLC 20 August 2001

FURTHER ANALYSIS OF PHASE II CLINICAL TRIAL RESULTS OF DEVACADE PROVIDES CONFIRMATION OF ENHANCED PAIN RELIEF AND INDICATES IMPROVEMENT IN QUALITY OF LIFE

ML Laboratories PLC announces that the early indication of positive results from its Phase II clinical trial with Devacade in patients suffering neuropathic pain announced on 29th June has been confirmed by completion of the analysis of the data relating to all participating patients.

During treatment with Devacade at the higher dose 50% of patients reported significantly improved pain relief compared to their current therapy with no reports of severe side-effects.

The significant pain relieving action of Devacade was complemented by indications of improvements in quality of life measures.

Devacade is the first orally administered product in this class of compounds specifically targeted for neuropathic pain and offers a new way of treating this type of pain.

Positive results such as these in a diverse group of chronic pain sufferers support the view that Devacade could have an important role in the management of serious pain conditions.

To date Devacade's clinical experience has addressed the severe pain sector, the standard treatment for which is the administration of strong opiates, a market currently estimated to be worth  $\Box 200-\Box 400$ million per annum. ML's pre-clinical data indicates that Devacade may similarly enhance the pain relieving action of milder opiates such as codeine and enable it to access a much larger market estimated by ML at  $\Box 4$  billion p.a.

ML and its development partner Panos Therapeutics Ltd. are currently considering the next phase of clinical development of Devacade for the treatment of neuropathic pain which is due to commence later this year with a view to submitting an application for a marketing authorisation in 2003.

Eight UK hospital clinics participated in the study of 40 patients suffering moderate to severe neuropathic pain for which they were being treated by stable opioid and other analgesic therapy. During the study two strengths of Devacade and placebo were administered to the patients in addition to their existing treatment with all patients receiving each treatment for a period of two weeks.

Further detailed analysis of the study results continues and will be presented at the Fourth International Conference on the Mechanisms and Treatment of Neuropathic Pain to be held in San Francisco from Sept. 20-22nd 2001.

Dr. Nick Boyes ML's Group Director of R&D stated:

'Devacade and its related compound Colykade are the reference standard CCK-A and CCK-B receptor antagonists respectively in the research community. Having now met our primary objective of demonstrating the potential of Devacade to enhance the pain relieving effect of opioid analgesia we will shortly be in a

. 13.~

position to proceed with the final clinical trials necessary to obtain marketing authorisation for this use the application for which we anticipate will be submitted in 2003.

Furthermore, information generated from the clinical studies completed to date will enable us to evaluate other important potential applications for these drugs such as the treatment of irritable bowel syndrome and anorexia in the case of Devacade, and the treatment of gastrin sensitive cancers in the case of Colykade.

We believe that each of these drugs has the potential to achieve significant sales'

-ends-

Dr. R.N. Boyes Group Director of R&D ML Laboratories PLC

Tel: 01727 839906

Issued by: John Goold

Weber Shandwick Worldwide Tel: 0207 329 0096

## FURTHER INFORMATION:

Devacade (devazepide) is a selective cholecystokinin(CCK) A receptor antagonist. Preclinical studies demonstrated that CCK antagonists were capable of enhancing the pain relieving activity of opioid analgesics such as morphine without significantly increasing the unwanted effects of these drugs.

Neuropathic pain typically results from either mechanical or viral damage to the nervous system. Most commonly, neuropathic pain presents as low back pain, diabetic neuropathy, cancer pain or post-herpetic neuralgia. It is often persistent and difficult to treat, causing suffering and distress.

Published figures from the USA show that almost 4 million US citizens suffer from neuropathic pain, which would equate to some 15 million sufferers in the developed world. Of these, over half would be suffering from persistent low back pain.

Current treatment for neuropathic pain includes antidepressants and anti-epileptics as well as opiate analgesics of increasing strength as clinicians strive to control the pain.